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| 09/855,027 | 05/14/2001 | Bernhard Hering | 1432.05US02 | 7980 |

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| EXAMINER | |
|---|---|
| BELYAVSKYI, MICHAIL A | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1644 | |

DATE MAILED: 11/12/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. 09/855,027 | Applicant(s) HERING ET AL. | |
|---|---|---|---|
| | Examiner Michail A Belyavskyi | Art Unit 1644 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *23 April 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1 and 3-64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1 and 3-64* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Restriction/Election FAx* .

## DETAILED ACTION

1. Applicant's amendments, filed 04/23/02 (Paper No 12 ) is acknowledged.

*Claims 1, 3-64 are pending.*

In view of Applicant's Amendment filed on 04/23/02 (Paper No 12 ) that was not timely entered, the previous Office Action mailed on 09/30/02 (Paper NO: 10) is vacated. The new Restriction Requirement set forth below. Examiner apologized for any inconveniences.

## *Restriction Requirement*

2. Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax numbers are (703-872-9306 (before final) and 703-872-9307 (after final)). A Fax cover sheet is attached to this Office Action for your convenience.

3. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claim 1 and 3-19, drawn to a method of transplanting a donor tissue , classified in Class 424, subclass 577.

II. Claims 20-26, drawn to a kit for treating a patients, classified in Class 435, subclass 810.

III. Claims 27-36, drawn to a method of treating a patient with donor cells, classified in Class 424, subclass 93.1.

IV. Claims 37-39, drawn to a method of treating a patient with tissue taken from the donor classified in Class 424, subclass 572.

V. Claims 40-44, drawn to a method of transplanting pancreatic islet cells, classified in Class 424, subclass 93.7.

VI. Claims 45-47, drawn to a medically modified non-human animal, classified in Class 800, subclass 8.

VII. Claims 48-55 drawn to a method of treating a cancerous conditions, classified in Class 424, subclass 520.

VIII. Claims 56-64 drawn to a method of treating an immune system, classified in Class 424, subclass 577.

4. Groups I, III-V, and VII-VIII are different methods. These invention are different with respect to ingredients, method steps, and endpoints; therefore, each method is patentably distinct.

5. Groups II and VI are different products. A kit for treating a patients and medically modified non-human animal differ with respect to their structures and physicochemical properties; therefore each product is patentably distinct.

6. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Moreover, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention. Therefore restriction for examination purposes as indicated is proper.

## Species Election

Applicant is further required under 35 USC 121 (1) to elect a single disclosed species to which the claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

7. If Group I is elected, applicant is required to elect a specific method of transplanting a donor tissue, wherein: A) the conditional treatment is accomplished by administering a specific drug recited in Claims 8 and 9; B) administering the immune blockade treatment is accomplished by administering a specific drug recited in Claim 10.

These species are distinct because a specific method of transplanting a donor tissue wherein: A) the conditional treatment is accomplished by administering a specific drug recited in Claims 8 and 9; B) administering the immune blockade treatment is accomplished by administering a specific drug recited in Claim 10 differ with respect to the specific drug; thus each specific

method employing a specific drug represents patentably distinct subject matter. Furthermore, the examination of a specific method of transplanting a donor tissue wherein: A) the conditional treatment is accomplished by administering a specific drug recited in Claims 8 and 9; B) administering the immune blockade treatment is accomplished by administering a specific drug recited in Claim 10 would require different searches in the scientific literature.

8. If Group II is elected, applicant is required to elect a specific kit for treating a patien, wherein: A) specific conditioning treatment drug is chosen from the group recited in Claim 21; B) specific immune blockage drug is chosen from the group recited in Claim 22;

These species are distinct because their structure, physicochemical properties and mode of action are different. The examination of species would require different searches in the scientific literature.

9. If Group III is elected, applicant is required to elect a specific method of treating a patient, wherein: A) administering the conditional treatment is performed with specific drug selected from a group recited in Claim 30; B) administering the immune blockade treatment is accomplished by administering a specific drug recited in Claim 31.

These species are distinct because a specific method of treating a patient, wherein: A) administering the conditional treatment is performed with specific drug selected from a group recited in Claim 30; B) administering the immune blockade treatment is accomplished by administering a specific drug recited in Claim 31 differ with respect to the specific drug; thus each specific method employing a specific drug represents patentably distinct subject matter. Furthermore, the examination of a specific method of treating a patient, wherein: A) administering the conditional treatment is performed with specific drug selected from a group recited in Claim 30; B) administering the immune blockade treatment is accomplished by administering a specific drug recited in Claim 31 would require different searches in the scientific literature.

10. If Group IV is elected, applicant is required to elect a specific method of treating a patient, wherein administering the immune blockade treatment is accomplished by administering a specific drug recited in Claim 39.

These species are distinct because a specific method of treating a patient, wherein administering the immune blockade treatment is accomplished by administering a specific drug recited in Claim 39 differ with respect to the specific drug; thus each specific method employing a specific drug represents patentably distinct subject matter. Furthermore, the examination of a specific method of treating a patient, wherein administering the immune blockade treatment is accomplished by administering a specific drug recited in Claim 39 would require different searches in the scientific literature.

11. If Groups VI is elected, applicant is required to elect a specific medically modified non-human animal, wherein specific mildly myeloablative conditioning treatment comprises fludarabine or cyclophosphamide and wherein the animal is selected from the group recited in Claim 47.

These species are distinct because their structure, physicochemical properties and mode of action are different. The examination of species would require different searches in the scientific literature.

12. If Group VII is elected, applicant is required to elect a specific method of treating a cancerous conditions, wherein: A) the conditional treatment includes administering a specific drug recited in Claims 51 and 52; B) administering the immune blockade treatment includes administering a specific drug recited in Claim 53.

These species are distinct because a specific method of treating a cancerous conditions, wherein: A) the conditional treatment includes administering a specific drug recited in Claims 51 and 52; B) administering the immune blockade treatment includes administering a specific drug recited in Claim 53 differ with respect to the specific drug; thus each specific method employing a specific drug represents patentably distinct subject matter. Furthermore, the examination of a specific method of treating a cancerous conditions, wherein: A) the conditional treatment includes administering a specific drug recited in Claims 51 and 52; B) administering the immune blockade treatment includes administering a specific drug recited in Claim 53 would require different searches in the scientific literature.

13. If Group VIII is elected, applicant is required to elect a specific method of treating a cancerous conditions, wherein: A) the conditional treatment includes administering a specific drug recited in Claims 61 and 62; B) administering the immune blockade treatment includes administering a specific drug recited in Claim 63.

These species are distinct because a specific method of treating an immune system, wherein: A) the conditional treatment includes administering a specific drug recited in Claims 61 and 62; B) administering the immune blockade treatment includes administering a specific drug recited in Claim 63 differ with respect to the specific drug; thus each specific method employing a specific drug represents patentably distinct subject matter. Furthermore, the examination of a specific method of treating a cancerous conditions, wherein: A) the conditional treatment includes administering a specific drug recited in Claims 61 and 62; B) administering the immune blockade treatment includes administering a specific drug recited in Claim 63 would require different searches in the scientific literature.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

14. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskyi whose telephone number is (703) 308-4232. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Michail Belyavskyi, Ph.D.
Patent Examiner
Technology Center 1600
November 5, 2002

Christina Chan
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SUPERVISORY PATENT EXAMINER
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